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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,718

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Hideo Anraku

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SUGHRUE MION, PLLC  
2100 PENNSYLVANIA AVENUE, N.W.  
SUITE 800  
WASHINGTON, DC 20037

EXAMINER

WALKER, NED ANDREW

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,718	<b>Applicant(s)</b> ANRAKU ET AL.	
	<b>Examiner</b> NED A. WALKER	<b>Art Unit</b> 3781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/17/06, 04/13/06, 07/11/08</u> .                            | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. The Applicant's response and traversal to the Election of Species Requirement received May 22, 2008, has been fully considered and is persuasive. In light of the Applicant's arguments, the Examiner has decided to cancel the previous election of species requirement. The election of species requirement is hereby withdrawn. Claims 1-18 are pending.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, "a sealed container...comprising a thermoplastic resin", and "a surface layer comprising a thermoplastic elastomer or a thermosetting elastomer", and "a needle pipe insertable portion comprising a thermoplastic elastomer or a thermosetting elastomer" must be shown or the feature(s) canceled from the claim(s). If the feature is simply claiming a plastic composition, then this must be shown in the cross-sectional views as alternating thick and thin lines (see MPEP 608.02) or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are also objected to under 37 CFR 1.83(a) because they fail to show the crosshatching as plastic material in the cross sectional views as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

3. Furthermore, new corrected drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121 are required in this application because:

The drawings contain improper hatching within sectional views. Hatching must be used to indicate section portions of an object, and must be made by regularly spaced oblique parallel lines spaced sufficiently apart to enable the lines to be distinguished without difficulty. A cross section must be set out and drawn to show all of the materials as they are shown in the view from which the cross section was taken. The parts in cross section must show proper material(s) by hatching with regularly spaced parallel oblique strokes, the space between strokes being chosen on the basis of the total area to be hatched. Refer to 37 CFR 1.84(h(3)). See Figure(s) 1-21 and 24.

Figures 21, 22, and 23 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g).

The figures are improperly numbered since the figures contain multiple views within one figure. The different views must be numbered by labeling as separate figures using consecutive Arabic numerals, starting with 1, independent of the numbering of the sheets and, if possible, in the order in which they appear on the drawing sheet(s). Refer to 37 CFR 1.84(u). See Figure(s) 21.

The drawing sheet numbering is formatted improperly. The drawing sheet numbering must be clear and larger than the numbers used as reference characters to avoid confusion. Refer to 37 CFR 1.84(t). See pages 1-11.

4. Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s)

should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**6. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 1, lines 12-13, lacks proper antecedent basis for "...having a deflection temperature under load of 60 degrees Celsius or more under a load of 0.45 MPa or 0.46MPa" and is therefore indefinite. The examiner is unclear what the "having" is referring to. Furthermore, the phraser "temperature under load of 60 degrees Celsius or

more under a load of 0.45 MPa or 0.46MPa” uses inaccurate and unclear wording.

Please revise to provide proper clarity and to correct indefinite language.

Claim 2, lines 11-14, recites unclear and indefinite language. Specifically, “a deflection temperature under load of at least a portion of the leg portion B of the stopper contacting with the container under a load of 0.45 MPa or 0.46 MPa is higher than a deflection temperature under load of at least a portion of the container contacting with the leg portion A of the stopper under a load of 0.45 MPa or 0.46 MPa.” does not adequately provide or outline the relationships between the structure and does not clearly set for the comparison being made. It is unclear exactly what two parts or portions are being compared and it is also unclear what parts or portions the load of 0.45 MPa or 0.46 MPa is referring to since the language is ambiguous. Please clarify by using additional relational language, rearrangement of wording, and/or additional comma punctuation.

Claims 7 and 14-18 contain the preamble “A vacuum specimen-sampling container” yet they are subsequently written as dependent claims. Since they contain a new preamble that is not associated with the preamble of the dependent claims, they appear to be intended as independent claims, and should be rewritten as such by removing dependency to other claims. Otherwise, if the intention is to have the claims written as dependent claims, they must share the common preamble “The sealed container.” Appropriate correction is required.

Claims 3-18 are rejected for incorporating the errors from their respective parent claim by dependency.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1-3, 5-7, 9, 11, 13-15, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Anraku et al. (EP 1064879A1).**

Regarding claim 1, Anraku et al. ('879) teaches a sealed container, which comprises a container (10) with an end being closed and the other end being open, comprising a thermoplastic resin [0049], and a stopper (1) being detachable and capable of sealing the open end of the container, the stopper having a head portion (2) capable of being grasped, a leg portion A (4) being extended downward from the head portion, being along an internal wall surface of the open end of the container, and being capable of exerting a fitting force to the internal wall surface, and a leg portion B (6) being extended downward from the head portion, being along an external wall surface of the open end of the container, and being capable of exerting a fitting force to the external wall surface and at least a portion of the leg portion B of the stopper contacting with the container and at least a portion of the container contacting with the leg portion A of the stopper (FIGS. 1 and 4) having a deflection temperature under load of 60 degrees Celsius or more under a load of 0.45 MPa or 0.46 MPa ([0049], [0053], [0059], [0133]). The *eFunda Polymer datasheet* for HDPE and the *MatWeb Plastic Material Data Sheet* for polyurethane thermoplastic elastomer satisfy a deflection temperature

under load of 60 degrees Celsius or more under a load of 0.45 MPa or 0.46 MPa for both of these materials, and it is these materials that are disclosed by Anraku et al. ('879) as portions B and A, respectively.

Regarding claim 2, Anraku et al. ('879) teaches the limitations as applied to claim 1 above, and teaches furthermore that part B can be made of HDPE ([0049], [0133]), and this material exhibits a deflection temperature of 80-92 degrees Celsius under a load of 0.46 MPa (*eFunda*). Anraku et al. ('879) also teaches that part A can be made of polyurethane thermoplastic elastomer ([0053], [0059]), and this material exhibits a deflection temperature of 57-78 degrees Celsius under a load of 0.46 MPa (*Matweb*). Therefore one would glean from Anraku et al. ('879) that a deflection temperature under load of at least a portion of the leg portion B of the stopper contacting with the container under a load of 0.45 MPa or 0.46 MPa is higher than a deflection temperature under load of at least a portion of the container contacting with the leg portion A of the stopper under a load of 0.45 MPa or 0.46 MPa.

Regarding claim 3, Anraku et al. ('879) teaches wherein a distance of the leg portion B of the stopper contacting with the external wall surface of the container is shorter than a distance of the leg portion A of the stopper contacting with the internal wall surface of the container in the longitudinal direction of the container ([0080-0083], [0043], FIG. 1, FIG. 4).

Regarding claims 5 and 9, Anraku et al. ('879) teaches wherein the leg portion A (4) of the stopper has a surface layer comprising a thermoplastic elastomer or a



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thermosetting elastomer at least at a portion contacting with the internal wall surface of the container ([0043], [0059]).

Regarding claims 6, 11, and 13, Anraku et al. ('879) teaches wherein the stopper has a needle pipe insertable portion (3) comprising a thermoplastic elastomer or a thermosetting elastomer [0059].

Regarding claim 7, 14, 15, 17, and 18, Anraku et al. ('879) teaches a vacuum specimen-sampling container [0001], which comprises a sealed container (10), the inside thereof being in a reduced atmospheric pressure state. *The American Heritage<sup>®</sup> Dictionary of the English Language: Fourth Edition* defines vacuum as “a space in which the pressure is significantly lower than atmospheric pressure”, therefore Anraku et al. ('879) teaches the inside thereof being in a reduced atmospheric pressure state.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**12. Claims 4, 8, 10, 12, and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Anraku et al. (EP 1064879A1).**

Regarding claims 4 and 8, Anraku et al. ('879) teaches all the limitations of the claims except for wherein a position of the fitting force exerted between the leg portion A of the stopper and the internal wall surface of the container being greatest and a position of the fitting force exerted between the leg portion B of the stopper and the external wall surface of the container being greatest are located at different positions in the longitudinal direction of the container. The Examiner takes official notice it is old and notoriously well known, and is capable of instant and unquestionable demonstration as being well-known, that these forces for any stopper of similar design are located at different positions; otherwise opposing forces at the same location would cause the stopper to not function properly since it would be extremely difficult if not impossible to pressure fit close and manually pull open the stopper.

Claims 10, 12, and 16 are obvious according to claim 4 above and as applied to the teachings of Anraku et al. ('879) in claims 5, 6, and 7, respectively.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NED A. WALKER whose telephone number is (571)270-3545. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Stashick can be reached on 571-272-4561. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Anthony D Stashick/  
Anthony D Stashick  
Supervisory Patent Examiner, Art Unit 3781